

obvious from the nature of the error. No new matter has been added by the amendment.

On Form PTO 1449, filed December 16, 1999, a line was drawn through the following document—Herbert “Time-Resolved Infrared ATR Measurements of Liposome Transport Kinetics in Human Keratinocyte Cultures and Skin Reveals a Dependence on Liposome Size and Phase State,” J. Investigative Dermatology, Vol. 105, No. 2, pp 291-295 (1995)—thus indicating it was not considered. Upon review, Applicants noticed an inadvertent typographical error in the page numbers (that is, “195” should have been --295--). Hence, Applicants enclose a new Form PTO 1449 with the correct citation with a copy of the indicated reference and respectfully request that the Office consider this document.

### **III. Restriction and Election Requirements**

The Office has issued a restriction requirement for the reasons set forth beginning at page 2 of the outstanding Office Action. Specifically, the Office required an election of species for each compound of the composition recited in the claims (Office Action at 3).

The restriction and election of species requirements are respectfully traversed. However, to be fully responsive to these requirements, Applicants affirmatively elected, with traverse, claims reciting a composition comprising:

- a) vinylimidazolium methochloride/vinylpyrrolidone copolymer as the “at least one physiologically tolerated film-forming agent”;
- b) water as the “at least one physiologically tolerated solvent”;

- c) polyethoxylated hydrogenated castor oil as the "at least one plasticizer";  
and
- d) 4-[3-(4-hydroxybutyl)-4,4-dimethyl-2,5-dioxo-1-imidazolidinyl]-2-(trifluoromethyl)benzonitrile as the "at least one compound of formula I."

Applicants direct the Office to Example 1, wherein Applicants' elected species d) is prepared.

The Office Action indicates that claims 1, 7-8, and 11-21 are considered generic; however, Applicants also request the Office to reconsider claims 2, 4-6, and 10, which also embrace Applicants' elected species. In claim 2, note that the compound d) corresponds to R<sup>1</sup> as -CN; R<sup>2</sup> as -CF<sub>3</sub>; R<sup>3</sup> as =O; X as a radical of formula II (>C=O); Y as a radical of formula VI wherein R<sup>4</sup> is 4-hydroxybutyl; and Z as a radical of formula VII. In claim 4, see lines 2 and 3 which recite compound d). In claim 5, see "ethoxylated compounds" (line 2) which embraces c). In claim 6, see line 2 reciting "polyethoxylated castor oil" which also embraces c). In claim 10, see page 27, lines 1 and 2, reciting "vinylimidazolium methochloride/vinylpyrrolidone copolymer" which embraces a). In the event that the Office makes the restriction requirement final, Applicants request that the Office should at least examine claims 1-2, 4-8, and 10-21.

Applicants initially traverse the restriction requirement on the grounds that the Office has not shown that there would be a serious burden to examine the claims of the present invention together. By failing to list any additional classification for any nonelected species of the invention, the Office has failed to support its burden.

In addition, Applicants traverse the election requirement, because the Office has improperly carved up the claimed invention. As evidenced by the requirement set forth

in the Office Action, the Office has required restriction within the independent claims defining Applicants' invention. Applicants have a statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention in the manner they choose. Issuing a restriction requirement within a claim with the idea that Applicants would have to carve up that claim and pursue the nonelected subject matter in a separate application violates this right under Section 112. Indeed, the predecessor to the Federal Circuit has characterized such action as tantamount to a refusal to examine. *In re Weber*, 198 USPQ 328 (CCPA 1978).

35 U.S.C. § 121 gives the Office authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be independent and distinct. 35 U.S.C. § 121, however, does not give the Office authority to reject an individual claim on that basis. *Weber*, 198 USPQ at 332. In *Weber*, the Examiner and the Board rejected Weber's claims for containing improper Markush groups and also under 35 U.S.C. § 121. *Id.* at 329. The Office had taken the position that claim 1 embraced 24 enumerated independent and distinct inventions. *Id.* at 330. Giving the Office's position short shrift, the court reversed, reasoning that:

As a general proposition, an applicant has the right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim.

*Id.* at 331.

Accordingly, Applicants respectfully request that the full scope of the claimed invention continue to be examined in this application without restriction or election requirement. If the Office chooses to maintain the election requirement, Applicants expect the Office, if the elected specie is found allowable, to continue to examine the full scope of the subject matter to the extent necessary to determine the patentability thereof, that is, extending the search to a reasonable number of the non-elected species according to *M.P.E.P.* § 803.02 and 35 U.S.C. § 121.

In view of the foregoing remarks, Applicants respectfully submit that both the restriction and the election of species requirement are in error and request that the requirements be withdrawn.

#### **IV. Rejections Under 35 U.S.C. § 103(a)**

The Office rejects claims 1, 7-8, 11-13, 16-18, and 22-29 as allegedly obvious over the combination of Flemming (U.S. Pat. No. 6,117,436), Claussner-509 (U.S. Pat. No. 6,087,509), and Winters (WO 95/30409) in view of Claussner-553 (U.S. Pat. No. 5,750,553) and further in view of Bernardon (U.S. Pat. No. 5,763,487), Bazzano (U.S. Pat. No. 5,514,672), Lai (U.S. Pat. No. 5,916,910), Ismail (U.S. Pat. No. 5,541,220), Galey (WO 92/21317), Dumats (WO 91/19701), and Estradier (EP 427 625) for the reasons advanced in paragraph 2 of the outstanding Office Action. Under Section 103(a) and according to *M.P.E.P.* § 2143, the Office has the initial burden to establish a *prima facie* case of obviousness by pointing to three basic criteria, all of which are relevant here. Importantly, the prior art used by the Office, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion

or incentive that would have motivated the skilled artisan to modify the teachings of a reference and/or to combine the teachings of references. *M.P.E.P.* § 2143.01.

Furthermore, the prior art must set forth a reasonable expectation of success for the proposed modification and combination. *M.P.E.P.* § 2143.02.

Applicants respectfully submit that the Office failed to meet its burden of establishing a *prima facie* case of obviousness, because there is no proper suggestion or motivation to modify the teachings of the primary references or to combine those teachings with the teachings of the secondary and tertiary references; further, Applicants submit that even if the teachings of the references were modified or combined, there is no reasonable expectation of success for such a modification and combination.

Claussner-509 describes "fluorinated or hydroxylated phenylimidazolidines, their preparation process, . . . and their . . . use" (col. 1, lines 5-9). The products of the formula of Claussner-509 (col. 1, lines 10-51) are used as medicaments for treating "acne, hyperseborrhea, alopecia or hirsutism" (col. 9, lines 35-37). Claussner-509, as admitted by the Office, "does not teach a copolymer of vinylimidazolium methochloride/vinyl pyrrolidone or polyethoxylated hydrogenated castor oil" (Office Action at 8). So, one would have had to combine the teachings of Claussner-509 with another reference to remedy these deficiencies and thus to have a chance of reaching any presently rejected claimed invention. The Office attempts to satisfy the differences of the teachings of Claussner-509 by combining them with the teachings of Flemming.

Flemming lists, in unrelated portions of its disclosure, Luviquat ® 905 (that is, a copolymer of vinylimidazolium methochloride and vinyl pyrrolidone; hereinafter

"Flemming's copolymer") (col. 4, line 67-col. 5, line 1) and Cremophor RH 410 (that is, a polyethoxylated hydrogenated castor oil; hereinafter "Flemming's castor oil") (col. 10, lines 38-40).

The Office argues it would have been obvious to combine and modify the teachings of Flemming and Claussner-509 to achieve the presently claimed invention. As motivation, the Office argues that Flemming teaches that "the copolymer and [castor] oil impart chemical and physical stability to [Flemming's] cosmetic composition during storage and use" (Office Action at 8). Applicants disagree that this is sufficient motivation to combine the teachings of Flemming and Claussner-509.

The Office seems to derive its motivation from the passage of Flemming, which states:

An additional advantage of the cosmetic care preparation of the invention resides in its chemical and/or physical stability, both with regard to the material composition that can be used and with regard to the usable concentrations of compositions of the first and second component. Examples of this would be stabilities of the pH value or of emulsions, both during storage and when the ready-to-use product is used.

(Col. 3, lines 55-62.) This passage relates to the chemical and physical stability problems of Fleming's hair care preparation, not any modified hair care preparation including a product of the formula of Claussner-509. More specifically, this passage is, at best, a suggestion to combine the composition of Fleming's first component with the composition of Fleming's second component. Fleming fails to teach or suggest anything about the capability of Fleming's copolymer or Fleming's castor oil to stabilize any compound similar to compounds within the scope of the formula of Claussner-509. Further, the Office has pointed to no suggestion in either reference that the compounds of the formula of Claussner-509 need chemical (pH) or physical

(emulsion) stabilization. Thus, there is no suggestion or motivation to combine the teachings of these references, and the Office has failed to meet its burden in establishing a *prima facie* case of obviousness over the combination of these two references.

Beyond this reason, Flemming and Claussner-509 fail to set forth a reasonable expectation of success for such a combination. The alleged stability of Flemming seems to result from keeping both the first and second components **separate until use**, in contrast to the structure where Fleming's copolymer and Fleming's caster oil are in a single mixture. More specifically, Flemming describes various problems, like emulsion or pH stability, with other hair care preparations (col. 2, lines 1-44). In particular, Flemming distinguishes several prior art hair care preparations, as follows:

In these and other cases, conditioners and vehicle substances are **present together in mixture form**. Such cosmetic care preparations, however, are not suitable to attaining the object of the present invention.

(Col. 2, lines 41-44; emphasis added.) Fleming states its objective as follows:

This object is attained, in part, by providing a cosmetic care preparation according to the invention, which is in the form of a two-component preparation, wherein the first component includes at least one conditioner and the second component substantially includes typical non-conditioning cosmetic vehicle substances, and in which **the first and the second component, as precursor products, are separate until use and are not present in mixed form until in the final, ready-to-use product**.

(Col. 2, lines 52-60; emphasis added.)

Flemming's first component may, if one chooses, contain Fleming's copolymer, and his second component may, if one chooses, contain Fleming's caster oil. Hence, Fleming's approach to solving stability problems is to separate the ingredients. As a result, Fleming does not teach to combine Fleming's copolymer of the first

component with Flemming's castor oil of the second component to form a single mixture. Indeed, if anything, Flemming teaches to separate both components until use (col. 1, lines 6-14). Indeed, if anything Flemming teaches away from Applicants' claims.

Further, one would have had to affirmatively choose both "at least one physiologically tolerated film-forming agent" and "at least one plasticizer" as recited, for example, in present claim 1 from the numerous first and second components of Flemming in order to recreate the present invention. No reference of record sets forth either a motivation or a reasonable expectation of success for such a combination, let alone a further combination which includes a product of the formula of Claussner-509.

Turning to the Office's second statement of motivation, the Office argues that Claussner-509 teaches "excipients incorporated into a composition with the active ingredient (formula (I))," and Flemming teaches "other known cosmetic additives, adjuvants and vehicle substances can be added" (Office Action at 8-9). In other words, the Office argues that because both Claussner-509 and Flemming teach adding other substances to their respective compositions, it would be obvious to add anything from Claussner-509—including all of the compounds recited in Applicants' claim 1. Nothing, however, in the terms "excipients" and "cosmetic additives, adjustments and vehicle substances" (Flemming) directs one of ordinary skill in the art to to Applicants' composition comprising "at least one physiologically tolerated film-forming agent," "at least one plasticizer," and "at least one compound of formula (I)" as recited, for example, in present claim 1. Thus, the Office has failed to meet its burden of establishing a *prima facie* case of obviousness.



Turning to the Office's third statement of motivation, the Office argues that the skilled artisan "would have been motivated to substitute the additives" of the tertiary references (Ismail, Lai, Bazzano, and Bernardon) in to the teachings of Claussner-509 and Flemming to produce "pharmaceutical compositions with enhanced ability to influence hair growth" (Office Action at 9). The Office does not rely upon any combination of these references to repair the deficiencies of Flemming and Claussner-509. The mere acknowledgement that additives can be added does not direct one of ordinary skill in the art to those of Applicants' invention. Thus, none of these references provides the motivation necessary to establish a *prima facie* case of obviousness. Accordingly, the present rejection should be withdrawn for this reason.

Finally, the Office has set forth no specific motivation to modify and/or combine the teachings of any combination of Galey and/or Dumats and/or Estradier and/or Winter and/or Claussner-'553. Moreover, the Office does not rely upon any combination of these references to repair the deficiencies of Flemming and Claussner-509. Thus, the Office failed to meet its burden in establishing a *prima facie* case of obviousness, and the present rejection should be withdrawn with respect to these references.

### CONCLUSION

Applicants respectfully request reconsideration and reexamination of the pending claims. If there are any questions that can be resolved by a telephonic conference, please contact Sean A. Passino at (202)408-6065.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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By: 

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Enclosures:

- (1) Appendix containing the marked-up comparison required of Rule 121(b)(1)(iii);
- (2) Herbert "Time-Resolved Infrared ATR Measurements of Liposome Transport Kinetics in Human Keratinocyte Cultures and Skin Reveals a Dependence on Liposome Size and Phase State," J. Investigative Dermatology, Vol. 105, No. 2, pp 291-295 (1995); and
- (3) A Form PTO 1449 citing the Herbert Reference.

**APPENDIX: A Marked-Up Comparison Required of Rule 121(b)(1)(iii).**

The specification has been amended as follows:

A preferred composition is that comprising a compound of the formula I in which

$R^1$  is 1) -CN,

2) -NO<sub>2</sub>, or

3) a halogen;

$R^2$  is 1) -CF<sub>3</sub> or

2) a halogen;

$R^3$  is 1) =O or

2) =S;

X is the radical of formula II or III, or

X and Y together form the group of formula IV,

in which  $R^4$  is as defined [in claim 1] above;

Y is the radical of formula VI,

in which  $R^4$  is as defined [in claim 1] above; and

Z is the radical of formula VII.